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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/897,801 | 06/29/2001 | Thomas C. Pinkerton | 6794S-000019US | 1264 |

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,801

Applicant(s)

PINKERTON, THOMAS C.

Examiner

Carlos A. Azpuru

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-138 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 85-138 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Prosecution on the merits of this application is reopened on claims 85-138 considered unpatentable for the reasons indicated below:

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 85-138 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 64-117 of copending Application No. 09/897,753('753). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 85-116, 120-138 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-7, 10-16, 18-23, and 25-30 of copending Application No. 09/606/909 ('909). Although the conflicting claims are not identical, they are not patentably distinct from each other because '909 claims a method of intradermal administration which like subcutaneous administration reaches the systemic circulation, but at a higher and faster rate (higher bioavailability). Those of ordinary skill would have found it well within their skill to claim the instant method for delivering intradermally given the claims of '909. There are no unusual and/or unexpected results which would rebut prima facie obviousness. Indeed, those of ordinary skill would have expected the same therapeutic results from the instant method of administration, given the method as claimed by '909. The instant method of administration and method of delivery would have been obvious given the claims of '909.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 85-116, 120-138 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pettis et al (reference designation #7 on IDS).

Pettis et al disclose a method for delivering intradermally, with improvement over subcutaneous injection (see Abstract, claims 25 and 47). The medication would inherently spill into the systemic circulation by this method. The bioactives delivered may be any of those described in paragraph [0051], page 7, and specifically include dopamine agonists, growth hormone, as well as low molecular weight heparin. Nanoparticles are described at paragraph [0048], page 7. Needles and microneedles

are found at page 4, paragraph [0027]. Electroporation and thermal poration are found at page 4, paragraph [0025]. Bolus injection is described at page 3, paragraph [0022]. Improved pharmacokinetics over subcutaneous administration is considered an inherent property of the intradermal route of administration. The instant claims are clearly anticipated by Pettis et al.

Claims 85, 86, 90,-98, 102- 109, ,113- 116, 120, 124-130, 134-138 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gross (US Patent No. 5,848,991).

Gross discloses a method for delivering a substance into the skin comprising delivering the substance into an intradermal space within the skin through a small gauge needle inserted into the intradermal space. The outlet of the needle is inserted at a depth within the skin such that leakage of the substance to the surface of the skin is substantially prevented. The needle selected may be microneedles, catheter needles, and injection needles. The substance may be a hormones such as growth hormone (somatotropin)(see Figures 1-13; col. 3, lines 9-68; cols. 4-6, lines 1-68; col. 7, lines 1-21). The claims are clearly anticipated by Gross.

Claims 117-119 are rejected under 35 U.S.C. 102(a) as being anticipated by Sun et al (WO/ 01/13989).

Sun et al disclose a tissue electroporation device for delivery to a precise layer of the skin (see Abstract). Delivery to dermal tissue is disclosed at page 21, line 17. Drugs used for delivery in such a device include low molecular weight heparin (page 22, line 11; and somatostatin or hGH at page 22, line 18. the instant claims are anticipated by Sun et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 85-88, 90, 91, 93-100, 103-111, 114-116, 119-122, 124, 125, 127-132, 134-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alchas.

Alchas discloses a drug delivery system which facilitates intradermal injections (see Abstract). Needle length is limited so as to prevent penetration beyond the dermis. Bioactives for incorporation are listed at col. 5, and include dopamine agonists and antagonists, growth hormone, and low molecular weight heparin. The increased bioavailability over subcutaneous administration is an inherent property of the method of administration. It would therefore have been well within the skill of the

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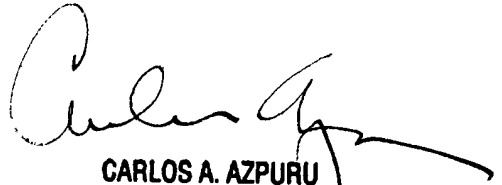
ordinary practitioner to claim a method of intradermal delivery and an intradermal device for delivering the claimed compounds wherein the bioavailability of the bioactives is higher than that of subcutaneous administration. There are no unusual and/or unexpected results which would rebut prima facie obviousness. The instant claims are there obvious in view of Alchas.

.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca


CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500